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TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

8648.61BSBY97 0 1 1 9 4 **0**

U.S. APPLICATION NO. (If known, see 37 C.F.R. 1.5)

		TION NO.

INTERNATIONAL FILING DATE

PCT/US96/13615

22 August 1996 (22.08.96)

PRIORITY DATE CLAIMED

22 August 1995 (22.08.95)

ORNEY'S DOCKET NUMBER

TITLE OF INVENTION

METHOD AND COMPOSITION FOR ENHANCED PARENTERAL NUTRITION

APPLICANT(S) FOR DO/EO/US

NAUCK, Michael A. and WAGNER, Fred W.

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

- 1. X This is a FIRST submission of items concerning a filing under 35 U.S.C. 371.
- 2. [] This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
- This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(l).
 - [X] A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
- . X A copy of the International Application as filed (35 U.S.C. 371(c)(2))
 - a. [] is transmitted herewith (required only if not transmitted by the International Bureau).
 - b. [] has been transmitted by the International Bureau.
 - c. \(\sqrt{\sq}}}}}}}}} \sepiction sethinder{\seta}}}}} \end{\sqrt{\sq}}}}}}}}}} \end{\sqrt{\sq}}}}}}}}}} \end{\sqrt{\sqrt{\sqrt{\sqrt{\sq}}}}}}}}} \end{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sq}}}}}}}}} \end{\sqrt{\sqrt{\sq}}}}}}}} \end{\sqrt{\sqrt{\sqrt{\sq}}}}}}}}} \engcoondstrut{\sqrt
- i. [] A translation of the International Application into English (35 U.S.C. 371(c)(2)).
- 7. [X] Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
 - a. [] are transmitted herewith (required only if not transmitted by the International Bureau).
 - b.
 have been transmitted by the International Bureau.
 - c. [] have not been made; however, the time limit for making such amendments has NOT expired.
 - d. [X] have not been made and will not be made.
- 8. [] A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
- 9. [] An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
- A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11. to 16. below concern document(s) or information included:

- 11. [] An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
- 12. [] An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
- 13. X A FIRST preliminary amendment.
 - [] A SECOND of SUBSEQUENT preliminary amendment.
- 14. [] A substitute specification.
- 15. [] A change of power of attorney and/or address letter.
- 16. [] Other items or information:

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U.S. APPLICATION NO. (If know	m con 37 C F P 1 5\V	INTERNATIONAL APPLICATION	NO	ATT DOGUMENT AND THE	
U.S. AT DICATION NO. (II MIOW	II, 566 57 C.P.R. 1.5)X	S DOCKET NUMBER 864a. AUSWO			
17. x The following	fees are submitted:	CALCULATIONS P	TO USE ONLY		
	EE (37 CFR 1.492(a) (1)-(been prepared by the EPO				
	inary examination fee paid	to USPTO	\$720.00		
	eliminary examination fee parch fee paid to USPTO (3				
	Il preliminary examination in fee (37 CFR 1.445(a)(2))				
		to USPTO (37 CFR 1.482) icle 33(2)-(4)	\$98.00		
	ENTER APPRO	PRIATE BASIC FEE	AMOUNT =	\$1,070.00	
	r furnishing the oath or dec claimed priority date (37 C	laration later than [] 20 [] CFR 1.492(e)).	30	\$	· · · · · · · · · · · · · · · · · · ·
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	17 -20 =	0	X \$22.00	\$	
Independent claims	3 -3 =	0	X \$82.00	\$	
MULTIPLE DEPENDE	NT CLAIM(S) (if applicat	ole)	+ \$270.00	\$	
	TOTAL	OF ABOVE CALCU	LATIONS =	\$1,070.00	
	ng by small entity, if application iled (Note 37 CFR 1.9, 1.2)	cable. Verified Small Entity 7, 1.28).		s	
		SI	UBTOTAL =	\$1,070.00	
	0 for furnishing the Englis claimed priority date (37 C	h translation later than [] 20 CFR 1.492(f).	[]30 +	\$	
		TOTAL NATIO	NAL FEE =	\$1,070.00	
		1.21(h)). The assignment n R 3.28, 3.31). \$40.00 per pro-		\$	
		TOTAL FEES E	NCLOSED =	\$1,070.00	
				Amount to be: refunded	\$
				charged	\$
a. X A check in the	amount of \$1,070.00 to co	ver the above fees is enclose	d.		<u> </u>
	Please charge my Deposit Account No in the amount of \$ to cover the above fees. A duplicate copy of this sheet is enclosed.				
 x The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 13-2725. A duplicate copy of this sheet is enclosed. 					
	·				
		37 CFR 1.494 or 1.495 has ore the application to pend		petition to revive (37 CFR	
			Si	GNATURE:	Span
3100 Norwest Center	IDENCE TO: MITH, EDELL, WELTER &	Steven C. Bruess IAME 34,130	n		
90 South Seventh Street 3100 Norwest Center Minneapolis Minnesota 5	5402	EGISTRATION NUMBER			

SMALL BUSINESS



VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS (37 C.F.R. 1.9(f) AND 1.27(c)) - SMALL BUSINESS CONCERN

I hereby dec	lare that I am	
a) [b) [concern identified below: concern empowered to act on behalf of the concern identified below:
	NAME OF CONCERN: ADDRESS OF CONCERN:	BioNebraska, Inc. 3820 Northwest 46th Street Lincoln, Nebraska 68524 United States of America
13 C.F.R. 12 35, United S For purposes concern of the concerns are	1.801-805, and reproduced in 37 C.F. tates Code, in that the number of emps of this statement, (1) the number of ene persons employed on a full-time, page 1.801-1.801.	siness concern qualifies as a small business concern as defined in R. 1.9(d), for purposes of paying reduced fees under Section 41(a) and (b) of Title loyees of the concern, including those of its affiliates, does not exceed 500 persons. Employees of the business concern is the average over the previous fiscal year of the part-time or temporary basis during each of the pay periods of the fiscal year, and (2) directly or indirectly, one concern controls or has the power to control the other, or a control both.
with regard t		nave been conveyed to and remain with the small business concern identified above ND COMPOSITION FOR ENHANCED PARENTERAL NUTRITION by er described in
a) [b) [c) [provisional application serial no. non-provisional application seria 22 August 1996.	, filed al no, filed <u>February 20, 1998,</u> based on PCT/US96/13615, filed
rights to the qualify as an under 37 C.I each named	invention is listed below* and no righ independent inventor under 37 C.F.R F.R. 1.9(d) or a nonprofit organization person, concern or organization havin	tiness concern are not exclusive, each individual, concern or organization having its to the invention are held by any person, other than the inventor, who could not in 1.9(c) or by any concern which would not qualify as a small business concern under 37 C.F.R. 1.9(e). *NOTE: Separate verified statements are required from g rights to the invention averring to their status as small entities. (37 C.F.R. 1.27)
ADDRESS: C	fichael A. Nauck berarzt, Medizin. UnivKlinik, Ruhr-Uni INDIVIDUAL b) SMALL BUSI	iversitat Bochum, Knappschaftskrankenhaus, In der Schornau 23-25, Bochum 44892, Germany NESS CONCERN c) NONPROFIT ORGANIZATION
NAME: ADDRESS: a) \[\overline{\o	INDIVIDUAL b) ☐ SMALL BUSI	INESS CONCERN c) □ NONPROFIT ORGANIZATION
entity status		or patent, notification of any change in status resulting in loss of entitlement to small ng, the earliest of the issue fee or any maintenance fee due after the date on which 37 C.F.R. 1.28(b))
are believed made are pur	to be true; and further that these stater nishable by fine or imprisonment, or b ents may jeopardize the validity of the	Tmy own knowledge are true and that all statements made on information and belief ments were made with the knowledge that willful false statements and the like so both under Section 1001 of Title 18 of the United States Code, and that such willful application, any patent issuing thereof, or any patent to which this verified
NAME: TITLE:	Fred W. Wagner	·
ADDRESS:	President 3820 Northwest 46th Street, Linc	oln, Nebraska 68524
SIGNATUR	-/1 /11/1/	Date: March 17, 1998
	MERCHAI	NT, GOULD, SMITH, EDELL, WELTER & SCHMIDT Professional Association

4/3

INDEPENDENT INVENTOR(S)

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS (37 C.F.R. 1.9(f) AND 1.27(b)) - INDEPENDENT INVENTOR

As a below named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 C.F.R. 1.9(c) for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, to the Patent and Trademark Office with regard to the invention entitled <u>METHOD AND COMPOSITION FOR ENHANCED PARENTERAL NUTRITION</u> described in

b) 🗀	the specification filed provisional application non-provisional application 22 August 1996	n serial no, filed	y 20, 1998, based on PCT/US96/13615, filed		
d) 🗆	patent no, issu	ed			
grant, convey inventor under	or license, any rights in 37 C.F.R. 1.9(c) if that	the invention to any person who	ligation under contract or law to assign, could not be classified as an independent or to any concern which would not qualify as ation under 37 C.F.R. 1.9(e).		
Each person, cobligation und	oncern or organization er contract or law to ass	to which I have assigned, granted iign, grant, convey, or license any	, conveyed, or licensed or am under rights in the invention is listed below:		
		on, concern, or organization cerns or organizations listed below	w*		
	named pers	eparate verified statements are re son, concern or organization having verring to their status as small en	ng rights to the		
NAME	BioNebraska,Inc.				
ADDRESS	3820 Northwest 46th : a) ☐ INDIVIDUAL	Street, Lincoln, Nebraska 68524, b)			
	a) [] INDIVIDOAL	b) 🛛 SMALL BUSINESS CONCER	n c) NonProfit Organization		
NAME ADDRESS		-			
ADDRESS	a) INDIVIDUAL	b) SMALL BUSINESS CONCERN	N c) □ NONPROFIT ORGANIZATION		
entitlement to	small entity status prior	to paying, or at the time of payin	of any change in status resulting in loss of g, the earliest of the issue fee or any o longer appropriate. (37 C.F.R. 1.28(b))		
information an willful false sta Title 18 of the	d belief are believed to atements and the like so United States Code, and	be true; and further that these star made are punishable by fine or i	are true and that all statements made on tements were made with the knowledge that mprisonment, or both under Section 1001 of s may jeopardize the validity of the fied statement is directed.		
Michael A. Nau NAME OF INV		NAME OF INVENTOR	NAME OF INVENTOR		
Signature of Inv	entor	Signature of Inventor	Signature of Inventor		
Date Maso	C. 19, 1998	Date	Date		

88 Rec'd PCT/PTO 20 FEB 1998

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: NAUCK, MICHAEL ET AL.

Serial No: Unknown

Int'l Filing Date: August 22, 1996 Concurrently

herewith

Docket No.: 8648.61USWO

Due Date: 21 February 1998

Title: METHOD AND COMPOSITION FOR ENHANCED PARENTERAL NUTRITION

CERTIFICATE UNDER 37 CFR 1.10:

"Express Mail" mailing label number: EM045417026US

Date of Deposit: 20 February 1998

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

Name: William Smith

Assistant Commissioner for Patents

Attn: BOX PCT

Washington, D.C. 20231

Sir:

We are transmitting herewith the attached:

Transmittal sheet in duplicate containing Certificate under 37 CFR 1.10. \boxtimes

A check in the amount of \$1070.00 to cover filing fee. \boxtimes

 \boxtimes A return postcard.

Other: Preliminary Amendment (4 pages), Form PTO-1390 (2 pages)

Please charge any additional required fees or credit overpayment to Deposit Account No. 13-2725 A

duplicate copy of this sheet is enclosed.

MERCHANT, GOULD, SMITH, EDELL, WELTER & SCHMIDT

3100 Norwest Center, Minneapolis, MN 55402 (612/332-5300)

Name: Steven C. Bruess

Reg. No.: 34,130

Initials: SCB:IPD:KMC:bb